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Direct: (973) 541-8047
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Shaun.Clancy@degussa.com
www.degussa.com

October 6, 2003

Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

Contain NO CBI

Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six month to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

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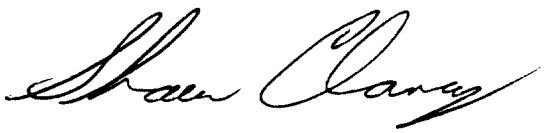
These studies were made available to Degussa Corporation in April 2003. Degussa's toxiciologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,



Shaun F. Clancy, Ph.D.

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404

Degussa Corporation

Memo

To: File

From: Shaun Clancy

CC:

Date: 10/06/03

Re: TSCA 8(e) Review – 41892-01-7

Two endpoints were provided by Fine Chemicals for 41892-01-7 3-Chloro-2-hydroxypropyldimethyl-dodecylammonium chloride.

- Eye Irritation
- Acute Fish Tox with Brachydanio rerio

This chemical is used as an intermediate in organic synthesis and is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will result. Appropriate Personal Protective Equipment is specified in the MSDS as is warnings not to allow the substance to be released. When used correctly the risk for human and environmental exposure is minimal.

The results of the eye irritation study indicate an effect which is unusual and is probably reportable under TSCA 8(e). The toxicity to fish, while in the "moderate" range, does not present a significant risk because of the use pattern of the chemical. This result is probably not reportable and will be submitted on an FYI basis.

Contains No CBI

degussa.

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sylvia.jacobi@degussa.com

www.degussa.com

Fine chemicals
Chemicals Safety Management

FC-TME-CSM/Dr.Jbi/sch

April 30, 2003

To: Shaun Clancy
S-SR-US-EHS

Fax-No. Recipient: 001-973 541 8040

Pages (total): 15

cc: Dr. W. Mayr/FC-TME-CSM

Initial notice of information for possible TSCA 8e submission
3-Chloro-2-hydroxypropyl-dimethyldodecyl ammonium chloride / Quab 342, CAS-No.: 41892-01-7

Dear Shaun,

please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability depending on the exposure situation.

I also attach a TSCA 8e submission of other data of the same substance of 1994 for your information.

I am at your disposal for any further questions.
I attach a short summary of the data together with the summary of the reports and an English translation of the German report on eye irritation.

Best regards
Sylvia Jacobi

degussa.

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63457 Hanau-Wolfgang
Germany

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F +49 6181 59-2083

Fine chemicals
Chemicals Safety
Management

April, 30, 2003

Initial Notice of Information to be assessed for Possible TSCA, Sec. 8e Reporting

Name / Trade name of the Substance	3-Chloro-2-hydroxypropyl-dimethyldodecyl ammonium chloride / Quab 342
CAS-No.:	41892-01-7

Human Health Effects	X
Environmental Effects	X

Degussa-Study-No.:	87-0117-DGO, 1987 85-0143-DKT
Other Source of information:	

Summary of Adverse Effects:

Human Health Effects:

Primary Eye irritation study in rabbits
Source, Degussa AG, unpublished report No. 85-0143-DKT
Guideline: OECD No. 405, non-GLP

In a first experiment 0.1 ml of the undiluted test substance was administered to the right conjunctival sac of the eyes of three animals. Corneal opacity grade 3 was observed in all 3 animals. Corneal opacity was still present at the end of the observation period (day 21). Iris congestion and folding (irritation score 1) was observed in all animals, but was reversible on day 11. Conjunctival reddening grade 3 was observed in all animals, chemosis grade 4 in one animal, grade 3.3 in 2 animals and secretion grade 3 in all animals was observed. The effects on the conjunctivae were reversible within the observation period (21 days).

In a second experiment 2 groups of 3 animals received 0.1 ml of the undiluted test substance in the right conjunctival sac following rinsing after 4 or 30 seconds. The eye reactions observed were comparable to those of the first test. However, following the rinsing procedure detachment of the conjunctival mucosa from the matrix and bleeding was observed.

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As these effects may be regarded as being potentially irreversible and the bleeding after rinsing of the eyes is an unusual finding, we would now regard this effect as reportable under TSCA 8e following the revised criteria.

Environmental Effects:
Source, Degussa AG internal report No. 87-0117-DGO, 1987
Guideline: OECD 203, GLP
Acute toxicity to fish:

LC_{50} brachydanio rerio: 7.1 mg/l, 96 h

This suggests a moderate concern level.
The quaternary structure of the substance does not suggest a bioaccumulation potential.

Nature and Extent of Risk Involved:
Will depend on the exposure situation.

Remarks:
According to our records the substance is included in the confidential part of the TSCA inventory (EPA Control No. 528 400 314) according to a TSCA 8e submission in 1994 (attached).

Information by	Date:
Dr. Sylvia Jacobi, FC-TME-CSM	30.04.03

Report No.: Ind.-TOX-081-82/83

DEGUSSA AG – US – IT – NR.		
85	0143	DKT

Lauryl-Quab

Acute Toxicity

Test of the irritant effect after single application on the rabbit eye

REPORT

November 22, 1985

1. GENERAL

Requested by:	DEGUSSA AG / ZN Wolfgang Industrielle Toxikologie (US-IT) Postfach 13 45 D-6450 Hanau 1
Testing facility:	ASTA-WERKE AG Chemische Fabrik Toxikologie Degussa-Asta Artur-Ladebeck-Str. 128-152 D-4800 Bielefeld 14
Test substance:	Lauryl-Quab
Type of test:	Test of the irritant effect after non-repeated application on the rabbit eye
Test guideline(s):	OECD Guideline No. 405 (3)
Report number:	Ind.-TOX-081-82/83
Schedule:	Start: 7/5/83 (primary and further tests) End: 8/2/83
Chief Test Administrator:	Dr. med. vet. H.J. Zechel
Study performed by:	A. Lagoudis
Report date:	11/22/1985

2. SUMMARY

Lauryl-Quab was tested for its irritant properties on the rabbit eye. 0.1 mL each was introduced into the right conjunctival sacs of three test animals. Based on the strong irritant action observed, further testing with 4 and 30 seconds of action time and subsequent rinsing to remove the test product were performed on a total of six more test animals.

Changes Observed:

In the primary test, the cornea exhibited strong opacification reactions. We also noted opalescent regions, between which features of the iris could no longer be recognized, as well as complete opacity of the cornea (iris not visible). The size of the opacified zone extended throughout the entire corneal area. One test animal reacted with pannus (keratitis). The findings extended beyond the 21-day observation time.

The iris reacted with abnormal folding, congestion, swelling and moderate circumcorneal hyperemia. Temporarily, two animals showed no reaction to incident light. The findings were detected up to a maximum of day 10 of the post-observation period.

The conjunctiva showed reddening, swelling and secretion. There was diffuse, flesh-colored reddening of all segments, swelling resulting in half-closed, sometimes completely closed eyelids, and hypersecretion that moistened major portions around the eye. From day 12 on, only reddening was visible, receding for the most part until day 21.

No signs of tissue changes in the sense of necrosis were observed in the primary test. The irritation index is 86. The results show strong irritant properties on the rabbit eye for Lauryl-Quab.

In both the test groups with 4 and 30 seconds of action time of the test substance and subsequent washing out, irritation indices of 85 (strong irritation) were calculated. However, detachment of the conjunctival mucosa from the matrix occurred during the wash-out phase, producing bleeding. This finding, occurring only in the further testing, suggests caustic properties of the test product on the rabbit eye.

Systemic toxic effects were not detectable.

Bielefeld, 11/22/1985

Chief Test Administrator:

[signature]

Dr. med. vet. H.J. Zechel

Institute Director:

[signature]

I.V. Dr. med. vet. W. Jahn

Bericht-Nr.: Ind.-TOX-081-82/83

Lauryl-Quab

Akute Toxizität

Prüfung der Reizwirkung nach einmaliger Applikation am Auge des Kaninchens

B E R I C H T

22. November 1985

1. ALLGEMEINES

Auftraggeber	:	DEGUSSA AG / ZN Wolfgang Industrielle Toxikologie (US-IT) Postfach 13 45 D-6450 Hanau 1
Prüfeinrichtung	:	ASTA-WERKE AG Chemische Fabrik Toxikologie Degussa-Asta Artur-Ladebeck-Str. 128-152 D-4800 Bielefeld 14
Prüfsubstanz	:	Lauryl-Quab
Art der Prüfung	:	Prüfung der Reizwirkung nach einmaliger Applikation am Auge des Kaninchens
Prüfrichtlinie/-n	:	OECD Guideline Nr. 405 (3)
Berichts-Nummer	:	Ind.-TOX-081-82/83
Zeitplan	:	Beginn: 05.07.83 (Primäre und Ende : 02.08.83 erweiterte Prüfungen)
Prüfleiter	:	Dr. med. vet. H.-J. Zechel
Durchführung der Studie	:	A. Lagoudis
Berichtsdatum	:	22.11.1985

2. ZUSAMMENFASSUNG

Lauryl-Quab wurde auf seine augenreizenden Eigenschaften am Kaninchen geprüft. Je 0,1 ml wurden in den rechten Konjunktivalsack von 3 Versuchstieren eingebracht. Aufgrund der hierbei beobachteten starken Reizwirkung fand eine erweiterte Prüfung mit 4 und 30 Sekunden Einwirkdauer und anschließender Auswaschung des Prüfproduktes an insgesamt 6 weiteren Versuchstieren statt.

Beobachtete Veränderungen:

In der Primärprüfung zeigte die Kornea starke Trübungsreaktionen. Es traten sowohl opaleszente Bezirke, zwischen denen Einzelheiten der Iris nicht mehr erkennbar waren, als auch völlige Undurchsichtigkeit der Kornea auf (Iris unsichtbar). Die Größe der Trübungszone erstreckte sich über die gesamte Korneafläche. Ein Versuchstier reagierte mit Gefäßeinsprossung (Keratitis). Die Befunde überdauerten den 21tägigen Beobachtungszeitraum.

Die Iris reagierte mit abnormer Fältelung, Kongestion, Schwellung, und mäßig zirkumkornealer Hyperämie. Vorübergehend zeigten zwei Tiere keinerlei Reaktion auf Lichteinfall. Die Befunde waren maximal bis Tag 10 der Nachbeobachtungsperiode nachweisbar.

Die Konjunktiva zeigte Rötung, Schwellung und Sekretion. Es kam zu diffuser, fleischfarbener Rötung aller Abschnitte, Schwellung, die zu halb, im Einzelfall zu vollkommenen geschlossenen Lidern führte und Hypersekretion, die beträchtliche Teile um das Auge befeuchtete. Ab Tag 12 war nur noch Rötung nachweisbar, die sich im Verlaufe bis Tag 21 weitgehend zurückbildete.

Anzeichen einer Gewebsalteration im Sinne einer Nekrose konnten bei der Primärprüfung nicht festgestellt werden. Der Reizindex beträgt 86. Daraus resultieren für Lauryl-Quab stark reizende Eigenschaften am Kaninchenauge.

Für die Untersuchungsgruppen mit 4 und 30 Sekunden Einwirkdauer der Prüfsubstanz und nachfolgender Auswaschung ließen sich Reizindices von jeweils 85 (stark reizend) errechnen. Während der Auswaschungsphase kam es jedoch zu Ablösungen der Konjunktivalschleimhaut von der Matrix, so daß Blutungen auftraten. Dieser Befund, der nur für die erweiterte Prüfung zutrifft, gibt Hinweis auf ätzende Eigenschaften des Prüfproduktes am Kaninchenauge.

Systemisch-toxische Effekte waren nicht nachweisbar.

Bielefeld, den 22.11.1985

Prüfleiter:

Dr. med. vet. H.-J. Zechel

Institutsleiter:

I.V. Dr. med. vet. W. Jahn

division of technology for society

netherlands organization for applied scientific research

Report no. : R 87/111
Order no. : 17355
Date : 01-04-1987

THE ACUTE TOXICITY OF QUAB 342 TO *BRACHYDANIO RERIO*

Author: Ms D.M.M. Adema

Approved by: Dr A.J.M. Schoot Uiterkamp

Sponsor:

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CONTENTS

SUMMARY AND CONCLUSIONS

The acute toxicity of QUAB 342 to the fresh-water fish species *Brachydanio rerio* was determined as laid down in the OECD Guideline no. 203.
The 48h- and 96h LC50 were found to be 7.1 $mg.l^{-1}$.
At 10 $mg.l^{-1}$ all animals were dead after 96h exposure.
At 5.6 $mg.l^{-1}$ 90% of the animals were living after 96h exposure and their condition, visually assessed, was the same as that of the control animals.
The slope of the concentration-effect curve was 0.11.
QUAB 342 was miscible with water in any proportion (see Annexe E).

Degussa

Degussa
Corporation

Dblage
Quab 342

May 6, 1994

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street, S. W.
Washington, D.C. 20460

Attn.: Section 8(e) Coordinator

Re: Substantial Risk Notification
Pursuant to TSCA Section 8(e)

Dear Sir:

This Substantial Risk Notification is being submitted in accordance with Section 8(e) of the Toxic Substances Control Act (TSCA) by Degussa Corporation. In response to a bona fide intent to import, we were informed that the substance was listed on the confidential portion of the TSCA Inventory (EPA Control No. 528400314).

The chemical name is 1-Dodecanaminium, N-(3-chloro-2-hydroxypropyl)-N,N-dimethyl-chloride (which we identify by the trade names QUAB 342 and Lauryl QUAB) CASRN 41892-01-7.

We have just been made aware of some toxicity studies which can be considered to be reportable under TSCA Section 8(e) because of certain neurotoxic effects. Although we do not believe that the results reasonably support the conclusion that the substance presents a reasonable risk of injury to the health or the environment, based on EPA's guidelines of June 1991, we are submitting them to the TSCA Section 8(e) Office.

A summary of each study and a printout from the STN Chemical Abstracts Service Registry File follows; copies of the studies are attached. Because the oral and dermal toxicity reports are in German, we have provided English translations of the summaries.

Acute Oral Toxicity Study in Rats

Dosage/route/duration: The test material was administered by gavage diluted and undiluted to male and female rats at a volume between 2.15 and 4.65 ml/kg. Post-exposure observation was 14 days.

Results: Intoxication was characterized by disturbance of the autonomic nervous system and the general condition (tremor, stilted gait, sunken sides or abdominal distension, salivation, ruffled fur, diarrhea, loss of body weight). Ante mortem loss of reflexes, convulsions, mydriasis and dyspnoea occurred in some individuals. The course of intoxication was acute to prolonged.

At necropsy of the deceased animals, stomach and intestine contained a colorless, red or yellow liquid. The mucosa of these organs was reddened. In one animal the stomach was perforated. In some cases gathering of liquid was detected in abdominal and thoracal cavity.

The LD_{50} value for female rats was 3066 mg/kg and for male rats 2332 mg/kg.

Acute Dermal Toxicity Study In Rabbits

Dosage/route/duration: The test material was administered undiluted to the dorsal skin of male and female rabbits at doses between 931 and 4321 mg/kg for 24 hours under occlusive conditions. The post-exposure observation was 14 days.

Results: Intoxication was characterized by tremor, ruffled fur, and reduction of body strength. Intoxication was prolonged. Deaths occurred between 2 and 7 days after application. At the application site grey discoloration, reddening, and eschar formation occurred.

At necropsy unspecific changes in kidneys, liver, spleen, lungs, heart and small intestine were observed.

The LD_{50} value for male and female rabbits was 2523 mg/kg.

In Vitro Ames Test

Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 were tested with and without liver microsomal activation system (Arochlor induced rats) at concentrations between 1.0 to 216 micrograms per plate.

At a concentration of 46.4 microgram/plate a weak increase ($< x 2$) was observed in the test strain TA 1538 in the absence of S9-mix. At higher concentrations, the number of revertants were decreased. Cytotoxicity was observed at 46 microgram/plate and at higher concentrations.

In Vivo Micronucleus Test in Mice

21.5 mg/kg (males) or 31.6 mg/kg (females) of the test substance were administered intraperitoneal to mice. No significant increase in micronucleated polychromatic erythrocytes was observed in both male and female mice, respectively males and females combined, at 24, 48 or 72 hours after administration.

Sincerely,

John Lewinson

John Lewinson, Ph.D.
Manager, Product Regulatory Compliance

JL-94-178

cc: R. Marion, DCA
Dr. Pieter, DCRP
B. Santoro, DCRP

bcc: Dr. Mayr, US-IT